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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,614

01/31/2007

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EXAMINER

CHOU, WILLIAM B

ART UNIT

PAPER NUMBER

3779

MAIL DATE

DELIVERY MODE

01/20/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,614	RAIMONDI, MANUELA TERESA	
	Examiner	Art Unit	
	WILLIAM CHOU	3779	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 14-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☒ Claim(s) 1,9,12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/16/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 1 is objected to because of the following informalities: The term “co-operating” in Line 4 should be “being adapted to co-operate” because the image acquisition device is not part of instrument (1) as claimed.

Claim 9 is objected to because of the following informalities: “were” in Line 2 is a typo. The term “moved” in Line 2 should be “adapted to be moved” for this apparatus claim.

Claim 12 is objected to because of the following informalities: quotation marks enclosing the term “scissors type”.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 9, 11, 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claim 3, the phrase “or the like” renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by “or the like”), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim 9 recites the limitation "the position where the reference device (5) is retracted" beginning in Line 2 and "the position where the reference device (5) is unfolded" beginning in Line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "the shank (4)" beginning in Line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "preferably" in Line 2 is a relative term which renders the claim indefinite. The term "preferably" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 13 recites the limitation "and is of the disposable type". It is unclear whether the disposable characteristic refers to the surgical instrument or the polymer material. It is also unclear whether it is implied that there are multiple types of disposable polymers and/or surgical instruments.

Claim Rejections - 35 USC § 112(6)

Relevant to Claim 1, 35 U.S.C. 112, sixth paragraph, is invoked such that the "means for" beginning in Line 3 of the claim is a knob, the functional equivalent of a trigger in the art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Doi (U.S. Issued Patent 6,033,359).

As to Claim 1, Doi discloses **in Fig. 1** a similar mini-invasive surgical instrument for geometrical evaluation of an object inside a body of a human being or animal, the instrument comprising a handle **(13)**, a reference device **(3)** and means **(14)** for bringing said reference device into the vicinity of said object, said instrument co-operating with an image acquisition device for acquiring at least one image of said reference device when it is in the vicinity of said object.

As to Claim 2, the adaptation of the invention to measure a lesion of an internal tissue is addressed as a “diseased part or the like” **in Column 1 Lines 6-8**.

As to Claims 10, Doi discloses the surgical instrument according to Claim 1 discussed above, characterized in that it is also comprises a recall system for recalling the reference device from an unfolded position into a retracted position **in Column 3 Lines 36-63**.

As to Claim 11, Doi discloses the surgical instrument according to Claim 10 discussed above, characterized in that the recall system comprises a wire **(11)**

connected to the reference device and to the handle, said wire being slidable inside an axial cavity of a shank.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doi in view of Davidson et al. (U.S. Issued Patent 7,634,305, hereinafter Davidson). The surgical instrument according to Claim 1 is discussed above. While Doi discloses a reference device that is 2-dimensional, Doi remains silent as to the reference device being a screen, when said screen is interpreted to be rectangular in dimension. Davidson is applied as a secondary teaching to evidence the level of skill in the art.

Relevant to Claim 3, Davidson explicitly teaches a similar mini-invasive surgical instrument, characterized in that said reference device (**scale**) is a screen or the like as disclosed in Column 4 Lines 22-25 and 30-37. The grid-like pattern of a screen can be seen in **Fig. 1A**. In consideration of the teachings of Doi and Davidson, as a whole, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the reference device of Doi with the screen taught by Davidson in order to provide an alternative of visual markings for reference to the operator.

Relevant to Claims 4 and 5, Davidson explicitly teaches **in Column 4 Line 64 to Column 5 Line 2** that the reference device may utilize colors visible to the operator. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the reference device of Doi with a color substantially contrasting with the object to be evaluated geometrically in order to facilitate visibility by the operator. Dark grey or black colors would be known as two obvious examples of such colors.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Doi in view of Storz (U.S. Issued Patent 4,607,620). The surgical instrument according to Claim 1 is discussed above. Doi remains silent as to the handle being preferably of the “scissors type”, interpreted to mean a system incorporating the use of levers.

Storz is applied as a secondary teaching to evidence the level of skill in the art. In particular, **as to Claim 12**, Storz teaches a handle incorporating the use of levers **in Fig. 1 and Column 2 Lines 50-53**. In consideration of the teachings of Doi and Storz, as a whole, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the knob operating means of Doi with the levers operating means taught by Storz in order to provide an alternative mode of operation for axial movements of the instrument's components by the operator.

Claims 6, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doi in view of Abe (U.S. Patent Publication 2004/0220555). The surgical instrument according to Claim 1 is discussed above. Doi remains silent as to the utilization of a shank within a barrel. Abe is applied as a secondary teaching to evidence the level of skill in the art.

As to Claim 6, Abe discloses **in Fig. 4** a similar mini-invasive surgical instrument **(1)** according to Claim 1 as discussed above, characterized in that it comprises a guide barrel **(50)** and a shank **(2)**, **not shown**, sliding inside said barrel, the barrel being able to be inserted inside the body and having a proximal end in the vicinity of the handle and an opposite distal end which is open.

As to Claim 7, Abe discloses the surgical instrument according to Claim 6 discussed above, characterized in that the shank has a head-piece **(22)** with support arms **(223)** for supporting said reference device **(221)**, as **shown in Fig. 3 and Paragraph 35**.

As to Claim 8, Abe discloses the surgical instrument according to Claim 7 discussed above, characterized in that the support arms are pivotably mounted and are elastically movable between a first position where the reference device is retracted and a second position where the reference device is unfolded in the vicinity of the object to be evaluated, as shown **in Figs. 2 and 3 and Paragraph 37**.

In consideration of the teachings of Doi and Abe, as a whole, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the surgical instrument of Doi to be inserted into a channel of a larger endoscope barrel in order for co-operative use with imaging and illumination means. Subsequently, the components of the shank and their operation, namely the head-piece, support arms, and retractable structure of the support arms, are similarly disclosed in both Doi and Abe.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Doi in view of Abe, in further view of Storz. Abe is applied as a secondary teaching to

evidence the level of skill in the art. The surgical instrument according to Claim 6 is discussed above. Abe teaches the surgical instrument characterized in that the shank is moved from a position where the reference device is retracted inside the barrel into a position where the reference device is unfolded in the vicinity of the object to be evaluated **in Figs. 2 and 3 and Paragraph 37**. However, Doi and Abe remain silent as to a trigger means.

Storz is applied as a secondary teaching to evidence the level of skill in the art. In particular, Storz teaches a trigger means situated at the proximal end for axial movement, **in Fig. 1 and Column 2 Lines 50-53**. In consideration of the teachings of Doi, Abe and Storz, as a whole, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the knob operating means of Doi and Abe with the levers operating means taught by Storz in order to provide an alternative mode of operation for axial movements of the instrument's components by the operator.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Doi in view of Wendlandt et al. (U.S. Patent Publication 2006/0106286, hereinafter Wendlandt). Doi remains silent as to the surgical instrument being made with a polymer material and disposable.

Wendlandt is applied as a secondary teaching to evidence the level of skill in the art. In particular, Wendlandt teaches a similar surgical instrument according to Claim 1 discussed above, characterized in that it is at least partially made with polymer material and is of the disposable type **in Paragraph 31**. In consideration of the teachings of Doi and Wendlandt, as a whole, it would have been obvious to one of ordinary skill in the art

Art Unit: 3779

at the time of invention to modify the surgical instrument of Doi to be manufactured with a polymer as taught by Wendlandt in order to be suitably biocompatible if disposability sired.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See the enclosed 892 form. 5,113,846 is cited to show similar articulated arms. 2009/0076503 (Paragraph 146) is cited to show high visibility color desirability. Also note the following cited to show similar measuring means:

4,362,167

5,058,603

5,239,982

5,379,754

5,967,968

6,613,002

6,814,728

2006/0030753

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner William Chou, whose telephone number is 571-270-3367. The examiner can normally reached on Monday-Friday from 9:30 am to 6:00 pm.

Art Unit: 3779

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas J. Sweet can be reached on 571-272-4761. The fax phone number for the organization where this application or proceeding is assigned is 571-271-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/WILLIAM CHOU/

Examiner, Art Unit 3779

/Thomas J Sweet/

Supervisory Patent Examiner, Art Unit 3779